

IN THE UNITED STATES DISTRICT COURT FOR THE  
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	)	
	)	
<i>Plaintiff,</i>	)	
	)	
v.	)	Civil Action No. 5:22-cv-05055-JFM
	)	
INHANCE TECHNOLOGIES, LLC,	)	<b>ORAL HEARING SCHEDULED</b>
	)	<b>FOR 8/23/23</b>
<i>Defendant.</i>	)	
	)	
	)	
	)	

**INTERVENOR-PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION  
FOR SUMMARY JUDGMENT AND INJUNCTIVE RELIEF AND RESPONSE  
TO THE UNITED STATES' MOTION FOR PARTIAL SUMMARY  
JUDGMENT**

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Intervenor-plaintiffs submit this Reply Memorandum in support of their motion for summary judgment and the United States’ motion for partial summary judgment. Attached are a Supplemental Statement of Undisputed Material Facts (“SSUMF”) replying to defendant’s response to intervenor-plaintiffs’ initial Statement of Undisputed Material Facts (“SUMF”) and a Supplemental Appendix (“SA”).

## **I. INTERVENOR-PLAINTIFFS HAVE ARTICLE III STANDING**

The Supreme Court has held that if at least one plaintiff has standing, the suit may proceed. *Rumsfeld v. Forum for Academic and Institutional Rights, Inc.*, 547 U.S. 47, 52, n. 2 (2006). In *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650-52 (2017), the Court explained that “[t]he same principle applies to intervenors of right . . . . Thus, at the least, an intervenor of right must demonstrate Article III standing when it seeks additional relief beyond that which the plaintiff requests.” As the Third Circuit has elaborated, “if a putative intervenor of right ‘seeks additional relief beyond that which the plaintiff requests,’ then the intervenor “‘must demonstrate Article III standing.’” *Wayne Land & Mineral Grp. v. Del. River Basin Comm’n*, 959 F.3d 569, 574 (3d Cir. 2020) (citation omitted).

Here, a demonstration of Article III standing is *not* required because plaintiff United States and intervenor-plaintiffs seek the same relief in their Complaints. *Compare* ECF 3 with ECF 36. Like the Government, intervenor-plaintiffs claim that plastic containers fluorinated by Inhance contain long-chain perfluoroalkyl carboxylates (“LCPFACs”) subject to EPA’s 2020 Significant New Use Rule (“SNUR”) and that Inhance’s production of these substances during fluorination is prohibited by the SNUR and the Toxic Substances Control Act (“TSCA”) itself. Both the Government and intervenor-plaintiffs further claim that, after testing by EPA in 2021-2022 demonstrated the formation of LCPFACs in fluorinated containers, the Agency asked Inhance to cease LCPFAC production until it had complied with the SNUR but it refused and still continues to form LCPFACs during fluorination. Like the Government’s Complaint,

the relief sought by intervenor-plaintiffs is an order enjoining Inhance's violations of the SNUR and protecting container users and the general public from the health risks of exposure to LCPACs.

Even if the intervenor-plaintiffs were required to demonstrate standing, their declarations satisfy standing criteria under the caselaw. These declarations identify specific plastic products to which declarants have been exposed. Initial Intervenor Appendix ("A") at 8, 10, 17, 24 and 47. Defendant has admitted that it fluorinates containers used to package these types of products. SUMF ¶ 18 [Ex. 9, SNUN Attachment Number: 005 at A-217, 257] Since Inhance acknowledges that it is the sole company performing post-mold fluorination in the U.S., there is a high likelihood that defendant is the source of the containers to which declarants have been exposed. Inhance does not dispute that LCPFAC substances are present in the containers it fluorinates and that declarants would be exposed to these substances during normal use and handling of these containers. Declarants have explained that they are fearful about the health impacts of using containers fluorinated by Inhance but cannot take action to reduce the risk because containers they purchase do not identify whether they are fluorinated and contain LCPFACs. A-7, 10, 11, 18. 24. 48. 29.

These factual demonstrations have been deemed sufficient for Article III standing. *Duke Power Co. v. Carolina Envtl. Study Group*, 438 U.S. 59, 74 (1978) (plaintiffs had standing due to "generalized concern about exposure to radiation and the apprehension flowing from the uncertainty about the health and genetic consequences of even small emissions."); *Reilly v. Ceridian Corp.*, 664 F.3d 38, 45 (3d Cir. 2011) ("exposure to a toxic substance" establishes standing because it "causes injury; cells are damaged and a disease mechanism has been introduced."); *Carlough v. Amchem Prods.*, 834 F. Supp. 1437, 1451 (E.D.Pa. 1993).

## **II. UNDISPUTED EVIDENCE DEMONSTRATES THAT PFAS ARE PRODUCED FROM CHEMICAL REACTIONS DURING IN-MOLD FLUORINATION**

The formation of LCPFACs and other PFAS during Inhance’s fluorination process is undisputed. Inhance’s own testing, submitted to the Court in support of the Government’s motion for partial summary judgment, confirms the presence of these substances in fluorinated fuel tanks and other containers, wastes from Inhance operations and alumina from scrubbers capturing air emissions from the fluorination process. DOJ Appendix to Memorandum in Support of Motion for Partial Summary Judgment (“DOJ App”) at 54-185. Moreover, in its SNUNs, Inhance describes PFAS formation as “an apparently unavoidable aspect of fluorination of HDPE containers” and explains that the “HDPE reacts with the fluorine to form a layer of fluoropolymer [and] [a]t the same time, the carboxylic acids react with the fluorine also, unintentionally forming LCPFACs.” [A-209, Ex 49, SNUN Attachment Number: 010 at A-1194]. Indeed, if Inhance had credible evidence that the nine LCPFACs were *not* produced during fluorination, its SNUNs would have been unnecessary and unwarranted.

While Inhance claims that process enhancements implemented in March 2022 were effective “in reducing unintentional LCPFAC formation in fluorinated HDPE containers” (Defendant’s Response to Government Statement of Undisputed Facts ¶15), it makes no claim that they eliminated the presence of PFAS and admits that “there is no easy solution to the problem of [PFAS] formation” [Ex. 8 at A-213]. Moreover, the Inhance test data submitted by the Government was generated in the fall of 2022, well after Inhance purportedly changed its fluorination process, but demonstrates the highest LCPFAC levels (5500 parts per billion for fuel tanks) reported in any Inhance and third-party testing. DOJ App at 59. And even if the new Inhance process reduced PFAS concentrations in containers, this would not be a defense against liability since EPA declined to exempt *de minimis* levels of PFAS from the SNUR. 85 Fed. Reg. 45109, 45120 (July 27, 2020).

Even without Inhance’s own testing, the six independently conducted studies described in the Leiva declaration conclusively demonstrate the presence of numerous PFAS in fluorinated containers and

their contents.<sup>1</sup> SUMF ¶ 35 [Ex. 7 at A-139-40]. Three of the six studies (Rand and Maybury (2011), Vitale (2022) and Whitehead and Peaslee (2023)) have been published in peer reviewed scientific journals that report their test procedures, data and conclusions in detail. The acceptance of the three studies for publication following peer review is evidence of their scientific reliability and admissibility. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 589-95 (1993). Two of the six studies, released in 2021 and 2022, were performed by EPA, which issued detailed reports presenting their methods and findings. [Ex. 8, at SA-102-12; Ex.9, at SA-113-23]. These studies are admissible as government reports under Federal Rule of Evidence 803(8). The final study, performed by the certified laboratory Eurofins, has not been published, but a detailed report on the study methods and results is in the record. A-155-214.

Despite challenging their admissibility, Inhance does not dispute the methodologies used in these studies or their findings but merely claims that intervenor-plaintiffs fail to “show that the studies reflect Inhance’s fluorination technology.” Defendant’s Response to Intervenor’s Statement of Undisputed Material Facts, at ¶¶ 35-37. In fact, the containers tested by Rand and Maybury (2011) and EPA (2021) were supplied by Inhance. [Ex. 8 at SA-103; Ex 2, Declaration of Kyla Bennett at SA-7 ¶ 7]. And the containers used in the Whitehead and Peaslee (2023), Eurofins (2023) and Vitale (2022) studies were fluorinated using the post-mold process. [Ex. 5, at SA-67; Ex. 2 at SA-6 ¶3]. Inhance acknowledges that it “is the only post-mold fluorination services provider in the United States for articles that are containers and fuel tanks.” Appendix to Inhance Opposition to Intervenor-Plaintiffs’ Motion for Summary Judgment (“Inhance App.”) at 6. While speculating that the containers tested in these studies might have been

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<sup>1</sup> Inhance asserts that the Leiva declaration is inadmissible opinion testimony. Defendant Response to SUMF at ¶¶35-36. However, the great bulk of the declaration consists of a factual description of the methodologies used and results obtained in the six studies and thus does not constitute expert opinion. In any case, intervenor-plaintiffs’ Supplemental Appendix includes the full reports of the six studies so that the Court can examine their results directly. [SA Exs. 4-6, 8-9].



imported from the EU or Asia, *id.*, Inhance provides no evidence that the post-mold process is used in these regions and was the source of containers tested for PFAS by U.S. laboratories.

### III. INHANCE’S CLAIMS THAT IT IS NOT SUBJECT TO THE SNUR LACK MERIT

Although Inhance now argues that disputed issues of fact preclude the Court from determining whether it is subject to the SNUR, the applicability of the SNUR turns entirely on the wording of TSCA and EPA regulations, which conclusively demonstrate that SNUR requirements apply to Inhance.

Inhance argues that the containers it fluorinates are “plastic articles,” “not chemical substances or mixtures,” and therefore its “fluorination process does not produce a chemical substance during the processing of another chemical substance or mixture.” Inhance App. at 11. The plain language of the statute and EPA regulations is otherwise. TSCA applies broadly to “chemical substances” and “mixtures.” Section 3(2) defines “chemical substance” as “any organic or inorganic substance of a particular molecular identity” and section 3(10) defines “mixture” as “any combination of two or more chemical substances.” The term “plastic article” does not appear in TSCA but, since such articles are a “combination” of chemical substances, they would logically constitute “mixtures” of substances that have been “formed to a specific shape or design during manufacture.” 40 C.F.R. § 720.3(c). Where a chemical reaction occurs during treatment of the article and a new “chemical substance” is formed, the person causing the reaction would be “manufacturing” the substance, even if it is “produced coincidentally during the manufacture” of another chemical. 40 C.F.R. § 720.3(r)(2)

As Inhance has acknowledged, molded HPDE is exposed to fluorine gas (F<sub>2</sub>) during fluorination. “The HDPE reacts with the fluorine to form a layer of fluoropolymer, which acts as the barrier needed to prevent permeation of [the container contents].” At the same time, “the carboxylic acids [present in the HDPE] react with the fluorine” to form LCPFACs.” A-209. In short, the chemical reaction that creates the desired fluoropolymer barrier unintentionally causes the formation of LCPFACs. This makes the LCPFACs

“byproducts,” which EPA defines as “a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.” 40 C.F.R. § 720.3(d). Because “byproducts” are generally subject to SNURs under 40 C.F.R. § 721.45(e), Inhance must comply with the SNUR because it manufactures LCPFACs as byproducts.

On two occasions before filing suit against Inhance, EPA advised the regulated community that LCPFACs formed during fluorination are “byproducts” and must comply with the SNUR under its regulations. A-741-745; A-769-777. Even were there any doubt about the plain meaning of these regulations, courts must defer to an agency interpretation so long as it is “logically consistent with the language of the regulation[s] and . . . serves a permissible regulatory function.” *Rollins Env'tl. Servs., Inc. v. EPA*, 937 F.2d 649, 652 (D.C. Cir. 1991).

Inhance argues that an LCPFAC formed during fluorination is an “impurity,” which is “a chemical substance which is unintentionally present with another chemical substance.” 40 C.F.R. § 720.3(m). Impurities are exempt from SNUR requirements under 40 C.F.R. § 721.45(d). However, there is no reason why an impurity cannot also be a “byproduct” if it meets EPA’s definition of that term. (Indeed, Inhance’s SNUNs list LCPFACs as both impurities and byproducts (Inhance App at 47)). In this event, impurities that are produced coincidentally during a chemical reaction to form another substance would be byproducts subject to the SNUR but other impurities would be exempt. Consistent with this interpretation, 40 C.F.R. § 720.3(d) limits the impurity exemption to “a person [who] manufactures or processes the substance *only as an impurity*” (emphasis added).

Finally, there is no merit to Inhance’s claim that it did not receive “fair notice” of the application of the SNUR to LCPFACs formed during fluorination. The fair notice doctrine does not apply where “the regulated party received, or should have received, notice of the agency's interpretation in the most obvious way of all: by reading the regulations. If, by reviewing the regulations and other public statements issued by

the agency, a regulated party acting in good faith would be able to identify, with ‘ascertainable certainty,’ the standards with which the agency expects parties to conform, then the agency has fairly notified a petitioner of the agency’s interpretation.” *General Elec. Co. v. EPA*, 53 F.3d 1324, 1329 (D.C. Cir. 1995).

EPA’s final rule and two proposals broadly define the LCPFAC universe and provide a detailed list of specific LCPFACs to which the SNUR applies. 85 Fed. Reg. 45124-25. At 40 C.F.R. § 721.10536 (b)(4)(ii), the rule describes a “significant new use” of LCPFACs as “[m]anufacture (including import) or processing *for any use* after December 31, 2015” (emphasis added). Thus, it was clear that *all* industry sectors that manufacture or process LCPFACs for a post-2015 use had to submit SNUNs. The only exceptions are in 40 C.F.R. § 721.10536(b)(5), which lists specific LCPFAC uses that existed before December 31, 2015 and continued after that date.

During the SNUR rulemaking, EPA urged companies to submit evidence that their LCPFAC uses met EPA’s exemption criteria so they could be excluded from the rule. 80 Fed. Reg. 2885, 2894 (January 21, 2015). Several manufacturers and importers heeded EPA’s request and submitted documentation of preexisting LCPFAC uses that would continue after the 2015 proposal date. Inhance did not. It blames its inaction on EPA’s failure to publicize the application of the SNUR to the “fluorination industry.” Inhance App. at 13-14. However, this would obligate agencies to research every conceivable activity that might be subject to a rule and take extraordinary steps (beyond Federal Register publication and normal outreach) to alert every potentially affected party to the rule’s application. No decision applying the fair notice doctrine has imposed such unreasonable burdens.

Ironically, while Inhance faults EPA for not disclosing the application of the rule to fluorination, there is no reason to believe it would have made any difference. This is because Inhance purportedly had no idea “that the fluorination of HDPE containers could result in the unintentional formation of LCPFACs” until EPA tested Anvil 10 + 10 pesticides a few weeks after the SNUR took effect. *Id.* at 15. If the sole company using

post-mold fluorination in the U.S. was not aware of the formation of PFAS after thirty years in the business, it is hard to understand why EPA had a duty to inform the industry that it was subject to the SNUR. While putting the monkey on EPA's back, Inhance never explains how a company whose core expertise was fluorine chemistry -- and had fluorinated hundreds of millions if not billions of fluorinated containers over its history -- could be ignorant of PFAS formation even after the 2011 Rand and Mabury study identifying PFAS in containers provided by the company. Plainly, any lack of diligence here was by Inhance, not EPA.

#### **IV. THE COURT MUST ORDER INJUNCTIVE RELIEF TO ACHIEVE COMPLIANCE WITH TSCA**

In arguing against injunctive relief, Inhance disregards the central tenet that when a statutory violation is found, a court must order relief that will achieve compliance with the law. The seminal case Inhance relies on, *Weinberger v. Romero-Barcelo*, 456 U.S. 305 (1982), held that courts should order relief “necessary to secure prompt compliance with the Act.” *Id.* at 320. In that case, the Navy discharged weapons material into the sea without a Clean Water Act permit. The Supreme Court ruled that enjoining any further discharges was “not the only means of ensuring compliance,” and that an order directing the Navy to apply for a permit was adequate to satisfy the Act. *Id.* See *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 543 (1987) (the basis for the holding in *Romero-Barcelo* was that “an injunction against all discharges was not the only means of ensuring compliance with the Act”). The choice of courts “is simply whether a particular means of enforcing the statute should be chosen over another permissible means; their choice is not whether enforcement is preferable to no enforcement at all.” *United States v. Oakland Cannabis Buyers’ Coop.*, 532 U.S. 483, 497-98 (2001).

As the First Circuit emphasized in a case relied on by Inhance, “[w]e agree that . . . , in all cases in which the Supreme Court has spoken in this area -- the violating party was not permitted to evade the substantive requirements of the statute” and that “the district court's order in all three cases was designed to lead to compliance.” *United States v. Massachusetts Water Res. Auth.*, 256 F.3d 36, 55 (1st Cir. 2001).

The First Circuit further underscored that, under the Safe Drinking Water Act, the statute at issue, “it should be a rare case in which a violation of regulatory standards does not lead to an injunction if the responsible enforcement agency requests one.” *Id.* at 58.

Here, there is no remedy available that could achieve compliance with TSCA other than injunctive relief. While section 16 of TSCA authorizes civil and criminal penalties for violations of the Act, 15 U.S.C. § 2615, these penalties cannot be sought or awarded in a government enforcement proceeding under TSCA Section 17, 15 U.S.C. § 2616, or a citizen suit under Section 20, 15 U.S.C. § 2619. (Indeed, it is doubtful that civil penalties would deter Inhance’s ongoing TSCA violations given its failure to heed EPA’s repeated requests to come into compliance.) By contrast, the remedies that the Court *can* invoke under sections 17(a)(1) and sections 20(a)(1) consist only of injunctive relief that (with one exception) has the sole purpose of requiring the defendant to comply with the law.<sup>2</sup> Congress’s exclusive focus on injunctive relief in TSCA’s enforcement provisions is in keeping with the strong TSCA prohibition against any manufacture of substances subject to SNURs before EPA has fully assessed their risks.<sup>3</sup> *Int. Mem.* at 26-27. Thus, the policies of the statute can only be upheld by an injunction compelling Inhance to stop producing PFAS while the SNUR process for determining risks is still underway.

Inhance conflates the standards for a preliminary injunction with the framework for granting a permanent injunction following a definitive determination of liability for violating a federal statute. Inhance Opposition at 31-38. However, intervenor-plaintiffs seek only a permanent injunction because, as demonstrated above, there are no disputed facts that bear on Inhance’s compliance with TSCA and its

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<sup>2</sup> The additional injunctive remedy authorized under section 17(a)(1)(D) is to provide public notice of the violation and risk of injury but this remedy would not restrain the violation and could not achieve compliance.

<sup>3</sup> In choosing among available remedies for achieving compliance, a court must take as given the value choices embodied in the statutes and policies administered by the [agency].” *NLRB v. P\*I\*E Nationwide, Inc.*, 894 F.2d 887, 893 (7th Cir. 1990).

liability is clear as a matter of law. If the Court agrees, it must impose a remedy restraining Inhance's ongoing violations of TSCA, notwithstanding other factors defendant might want the Court to consider.<sup>4</sup>

A further reason why balancing the equities is impermissible here is that Inhance's statutory violations are knowing and willful, precluding the need to consider any equities in its favor. Int. Mem. at 29-34; *Louis W. Epstein Family P'ship v. KMart Corp.*, 13 F.3d 762 (3d Cir. 1994) (no need to balance the equities where a violation is intentional); *United States v. Bethlehem Steel Corp.*, 38 F.3d 862, 867-868 (7th Cir. 1994) ("it is an accepted equitable principle that a court does not have to balance the equities in a case where the defendant's conduct has been willful").

The evidence of willful unlawful conduct in this case could not be starker. As recounted in Int. Mem. at 29-34, the Agency repeatedly informed Inhance that it was in violation of SNUR requirements and needed to stop forming PFAS during fluorination. EPA's March 1, 2022, Notice of Violation ("NOV") repeated EPA's determination that Inhance was in violation of the SNUR, explained why the SNUR was applicable to Inhance and directed it to "immediately cease the manufacture of LCPFAC substances subject to the SNUR, . . . submit a SNUN to the EPA and receive an EPA determination on that SNUN." [SA Ex. 1, EPA Notice of Violation at SA-3]. EPA reinforced its position in its March 16, 2022, open letter notifying companies that PFAS formation during "the fluorination of polyolefins [would] be a significant new use under TSCA" and companies needed to stop production and comply with the SNUR. A-743. Yet even after filing SNUNs in late 2022, Inhance defied EPA's explicit instructions by continuing to

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<sup>4</sup> Inhance even tries to leverage the denial of a preliminary injunction sought by intervenor PEER in another case. Inhance Opposition at 34-35, citing *America Unites for Kids v. Lyon*, No. CV 15-2124 PA (AJWx), 2015 U.S. Dist. LEXIS 66446, 2015 WL 2352184 (C.D. Cal. May 8, 2015). Inhance neglects to mention that PEER and its co-plaintiff in that case were later *granted* a permanent injunction. *America Unites for Kids v. Lyon*, No. CV 15-2124 PA (AJWx), 2016 U.S. Dist. LEXIS 118447 at \*34, \*35 (C.D. Cal. Sep. 1, 2016). That injunction as later modified was affirmed on appeal and PEER's dismissal on standing grounds was reversed. *Am. Unites for Kids v. Rousseau*, 985 F.3d 1075, 1082 (9th Cir. 2021).

manufacture PFAS before “EPA has conducted a review of the notice, made an appropriate determination on the notice, and taken such actions as are required in association with that determination.” *Id.*

Inhance may seek to excuse this history of intransigence by claiming it had an honestly held view that PFAS formed during fluorination were “impurities” exempt from the SNUR. But EPA expressly rejected that interpretation in its March 2022 NOV and letter to industry and fully explained its reasoning. Thus, Inhance chose to proceed with PFAS production knowing that EPA had made a carefully considered judgment that its actions were unlawful. In *Louis W. Epstein*, the Third Circuit found that a violation is intentional or willful even if a party disputes that it is in fact a violation: “A court balances equities to avoid harsh results that strict application of law could inflict on a blameless party. . . courts do not balance equities when the defendant ‘takes a chance’ that its action will be permissible under an existing easement or restriction.” 13 F.3d at 770; *see also Cal. Coast Univ. v. Aleckna (In re Aleckna)*, 13 F.4th 337, 343 (3d Cir. 2021) (a good faith belief is not a defense against a finding of willfulness; the defendant must point to authority that reasonably supports its belief that its actions were lawful).

Here, Inhance “took a chance” on continued production of LCPFACs with full knowledge that EPA disagreed with its position and in the face of the contrary wording of EPA’s regulations. If the Court now imposes liability on Inhance, it should not be allowed to escape enforcement by claiming that the “equities” warrant continued violation of TSCA.

## **V. SERIOUS RISKS TO PUBLIC HEALTH WARRANT INJUNCTIVE RELIEF**

“[W]hen environmental injury is ‘sufficiently likely, the balance of harms will usually favor the issuance of an injunction to protect the environment.’” *Sierra Club v. U.S. Forest Serv.*, 843 F.2d 1190, 1195 (9th Cir. 1988) (quoting *Amoco Prod. Co.*, 480 U.S. at 545). The Third Circuit has consistently recognized that injunctive remedies in statutes like TSCA “invoke nothing less than the full equity powers of the federal courts in the effort to protect public health, the environment, and public water supplies from

the pernicious effects of toxic wastes . . . [t]hese provisions have enhanced the courts' traditional equitable powers by authorizing the issuance of injunctions when there is but a risk of harm, a more lenient standard than the traditional requirement of threatened irreparable harm . . . Courts should not undermine the will of Congress by either withholding relief or granting it grudgingly.” *United States v. Price*, 688 F.2d 204, 211, 214 (3d Cir. 1982). Thus, ““if an error is to be made in applying the endangerment standard, the error must be made in favor of protecting public health, welfare and the environment.”” *Interfaith Community Organ. v. Honeywell Int'l*, 399 F.3d 248, 259 (3d Cir. 2005) (citation omitted).

Courts granting injunctions against violations of environment statutes do not demand that harm be certain: “a reasonable prospect of future harm is adequate to [warrant equitable relief] so long as the threat is near-term and involves potentially serious harm.” *Maine v. Mallinckrodt*, 471 F.3d 277, 296 (1st Cir. 2006); *United States v. Midway Heights County Water Dist.*, 695 F. Supp. 1072, 1076 (E.D. Cal. 1988) (“This court need not wait to exercise its authority until water district customers have actually fallen ill from drinking Midway Heights water”); *United States v. Union Corp.*, 259 F. Supp.2d 356, 399-400 (E.D. Pa. 2003) (observing that RCRA “does not require quantification of the endangerment (*e.g.*, proof that a certain number of persons will be exposed . . . or that a water supply will be contaminated to a specific degree)”) (quoting *United States v. Conservation Chemical Co.*, 619 F. Supp. 162, 194 (W.D.Mo. 1985)) and that “endangerment is substantial if there is some reasonable cause for concern that someone or something may be exposed to a risk of harm . . . if remedial action is not taken.”) (citation omitted).

Ignoring this caselaw, Inhance argues against injunctive relief because “none of the Intervenor allege any *actual* harm from exposure, nor can they point to anyone else who has actually experienced any adverse health effect.” Inhance Opp. at 33. This not only misstates the law but is incorrect: multiple epidemiology studies show that exposure to PFOA and other LCPFACs has caused statistically significant increases in cancer and other harmful health effects. SUMF at ¶¶ 79, 83, 103, 104.



Inhance goes even further to trivialize concerns about the risks of fluorinated containers:

Once again, there is no evidence about the actual amounts, if any, of PFAS that are produced by Inhance's fluorination technology. There is no evidence about which PFAS may or may not be produced. There is no evidence about the exposure of the public to those PFAS, if they are created, or if that exposure may result in unreasonable risks of harm to the environment or human health.

Inhance Opp. at 34. Every one of these statements is demonstrably *false*: (1) testing by Inhance, EPA and other researchers demonstrates the “amounts of PFAS . . . produced by Inhance's fluorination technology” (SUMF ¶¶ 29-48); (2) this testing provides detailed evidence of “which PFAS may or may not be produced” during fluorination and consistently demonstrates the presence of 13 PFAS in fluorinated containers and their contents, *id.*; (3) the fluorination of up to 200 million containers annually, the large number of products distributed in these containers and the many known pathways for direct human contact and environmental release during the container life-cycle provide compelling “evidence about the exposure of the public to those PFAS,” *id.* ¶¶ 105-123; and (4) the numerous studies attributing multiple adverse effects at very low concentrations to the PFAS in fluorinated containers demonstrate that this “exposure may result in unreasonable risks of harm to the environment or human health.” *Id.* ¶¶ 79-104.

Inhance cannot escape this overwhelming evidence of exposure and risk by dismissing it as “expert opinion” which is not admissible without discovery. Nearly all the evidence on which intervenor-plaintiffs rely is derived from the Inhance SNUNs, peer reviewed studies published in the scientific literature and government reports. While a portion of the Phelps/DeWitt report might be considered “opinion,” this report is principally a factual compilation of published studies and reports on the health effects of the 9 LCPFACs and 4 short-chain PFCAs found in fluorinated containers. A-51-136. In particular, Drs. Phelps and DeWitt document EPA's scientific and regulatory determinations in support of its proposed drinking water standards for PFOA, PFNA and other PFAS. A-62-67. Not only have EPA's scientific findings in this rulemaking been approved by its independent Science Advisory Board (Inhance App. 235-383), but they are admissible under Fed. R. Evid. 803(8)(C) as “records, reports, statements, or data compilations,

in any form, of public offices or agencies.” *Coleman v. Home Depot, Inc.*, 306 F.3d 1333, 1341 (3d Cir. 2002). Inhance’s consultants may question narrow aspects of EPA’s risk modeling for PFOA (Inhance App. at 538-547), but they cannot dispute the great bulk of human and animal studies showing that the 13 PFAS in fluorinated containers cause harm to development, reproduction, immune function, the cardiovascular system, the endocrine system, the nervous system, the liver and other endpoints.

For Inhance to dismiss these public health concerns as merely “general grievances with PFAS broadly” is irresponsible. Inhance Opp. at 22. EPA has termed PFAS “an urgent public health and environmental issue facing communities across the United States.” SUMF ¶¶ 74-78. The LCPFACs in fluorinated containers include PFOA, a poster child for PFAS contamination found in the blood of 98 percent of the US population that, according to EPA, lacks any safe level of exposure. *Id.* ¶¶ 84-90. Perhaps the risks of PFAS in these containers cannot be quantified with absolute certainty, but there is no dispute they create a “reasonable prospect of future harm,” *Maine*, 471 F.3d at 296, sufficient to require injunctive relief.

## **VI. INHANCE’S UNSUPPORTED CLAIMS OF ECONOMIC HARM DO NOT JUSTIFY WITHHOLDING INJUNCTIVE RELIEF**

Inhance claims that, even if it is violating TSCA, it should continue producing PFAS because enjoining its violations “would be massively disruptive to both the company and the national economy.” Inhance Opp. at 36. Inhance warns of “supply chain bottlenecks” in several industries because it will “take many months, if not years, to build a sufficient alternative capacity to fulfill customers’ needs for containers that have the same barrier protection attributes as those offered by Inhance.” *Id.* at 36-37. These claims are purely speculative; the only “evidence” backing them up are generalized assertions of a senior executive. Inhance even dismisses as “immaterial” evidence submitted by intervenors that viable non-fluorine barrier technologies are widely available to replace in-mold fluorination. SUMF ¶¶ 125-128.

The attached declaration of Kevin Callahan, Chief Operating Officer of BP Polymers LLC, describes the benefits of one such proven technology, polyamide-based barrier additives, which “can be easily introduced to extrusion blow molding and rotomolding operations with minimal adjustments” and require “minimal” capital investment. [Ex. 3, Declaration of Kevin Callahan at SA-44-45 ¶ 3]. With a growing customer base, BP has capacity to scale-up production to meet additional demand and is constructing new manufacturing facilities. It is in discussions with plastic container suppliers serving numerous packaging sectors and has “no doubt that US industry has viable alternatives besides fluorination that are PFAS free, readily available, and economical.” *Id.* at SA-50 ¶ 27.

As discussed above, Inhance’s willful SNUR violations preclude consideration of its economic concerns and TSCA itself directs that restrictions on SNUN substances must protect against unreasonable risks “without consideration of cost or other non-risk factors.” 15 U.S.C. §2604(f)(1). But even if economic impacts were relevant to the Court’s choice of remedy, the evidence shows that industry can easily and economically transition to non-fluorination barrier protection technologies if the Inhance post-mold process is prohibited by judicial order.

### CONCLUSION

For the foregoing reasons, the Court should grant the United States’ motion for partial summary judgment and intervenor-defendants’ motion for summary judgment and enjoin defendant Inhance’s ongoing violations of TSCA.

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Respectfully submitted,

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